

REMARKS

Claims 1-11 are pending in the case and all have been rejected.

Specification

The Examiner notes use of the term "ambien" in the specification and that such term should be described as "AMBIEN®." Applicant responds that the specification has been examined and this term is represented only in capital letters with the registration mark so that no amendment to the specification is believed due.

Claim Objections

Claim 10 was objected to for misspelling of the word "ritalin" as "ritilin" and in response Applicant has amended claim 10 to correctly spell this term.

Rejection Under 35 U.S.C. 112, ¶1

Claims 1-11 were rejected under 35 U.S.C. 112, first paragraph, as failing to meet the enablement requirement. In particular, the claims are drawn to use of imidazo[1,2-a]pyridine derivatives while the specification is "enabling for inducing pain relief with zolpidem...." (see Office Action at page 3, paragraph 3, line 2 thereof)

In response, Applicants have amended claim 1 to recite only use of zolpidem (i.e., N,N,6-trimethyl-2-p-tolyl-imidazo[1,2-a]pyridine-3-acetamide). Thus, the specification is fully enabling for amended claim 1 and Applicant respectfully requests that this ground of rejection be withdrawn.

Rejection Under 35 U.S.C. 102 (b)

Claims 1-3, 6 and 9-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Meisler (2000).

In response, Applicants have amended claim 1 to recite that the composition is administered orally or topically, already recited in claims 4 and 5 (so that no new matter is added), which claims were not rejected as anticipated, and which methods of application are not taught by Meisler (2000). (see Office Action at page 7, paragraph 5, line 4 thereof)

In view of this amendment, Applicants believe that this ground of rejection has been overcome and should be withdrawn.

Rejection Under 35 U.S.C. 103(a)

Claims 4 and 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Meisler (2000) in view of Holman (2002). The Examiner contends that Holman (2002) teaches administration of Zolpidem for sleep restoration while Meisler (2000) teaches zolpidem as a sleep medication for sufferers of chronic fatigue syndrome (who also struggle with chronic pain).

In response, Applicants urge that Holman only teaches use of zolpidem as a sleep medication and that this ground of rejection relies on combination with Meisler for the proposition that those with chronic fatigue syndrome also struggle with chronic pain. Initially, Applicants note that Holman teaches use of a sleep restorative agent only in combination with a therapeutic agent (and does not appear to teach use of such agent alone). For example, claim 1 (and dependent claims) of Holman is drawn to treating an autoimmune disease using the sleep restorative agent to increase the efficacy of the therapeutic agent (see also the Abstract of Holman as well as paragraph 10, lines 1-5

thereof) or to decrease the dosage of the therapeutic agent (see, for example, claim 4 of Holman) and does not even suggest chronic fatigue syndrome (the malady in the Meisler paper) anywhere in the specification.

Conversely, while Meisler teaches the occurrence of pain with chronic fatigue syndrome (CFS), this reference does not teach use of zolpidem to treat pain (only sleep problems) but does teach that CFS patients have "a low tolerance for any kind of medication" (page 479, column 2, bottom paragraph), that "long acting narcotics are needed to relieve pain among these patients" (at page 480, column 2, lines 10-12), that non-pharmacological methods are recommended to treat the pain aspects of the disease (page 481, bottom of column 1 over to column 2) and that NSAIDS may be used for treating the pain component of the disease (page 481, column 2, line 4). Thus, Meisler teaches away from use of zolpidem for treating pain in these, or any other, patients.

In short, one would not be motivated to combine these references by using zolpidem (orally or topically or any other way) to treat chronic pain of any cause. For example, if one combines Holman with Meisler by administering zolpidem (as much as is suggested by Holman alone), what would the result be? Based on Holman, one would be using it in combination with something else but what would that be? Holman does not teach using zolpidem alone and not in treatment of pain at all. The Examiner mentions Meisler as using Provigil and zolpidem (Office Action at page 7, lines 1-2 and page 8, lines 1-2) so, if the additional therapeutic agent is provigil, while zolpidem is the sleep restorative agent (that also reduces pain based solely on Applicant's teaching), then again there is no motivation to combine because these in one treatment because there is no teaching that zolpidem either increases the effect of provigil (see claim 1 of Holman) or reduces the effective dose of provigil (see claim 4 of Holman). Conversely, Meisler teaches use of Provigil as a stimulant (at page 480, column 2, second full paragraph) whereas zolpidem is a hypnotic (effects that are seemingly at odds with each other and would therefore not be synergistic). Alternatively, if one applies Meisler to administer NSAIDs (see page 480, column 2, lines 13-16) as an anti-inflammatory (i.e., therapeutic)

agent with zolpidem as a narcotic, again one is not motivated to administer zolpidem orally or topically (per Holman) because there is no teaching (or even evidence) that zolpidem either increases the efficacy, or decreases the required dose, of NSAID.

In sum, there is no motivation to administer zolpidem either orally or topically in combination with another drug, such as provigil, because Meisler does not suggest any increase in efficacy, or decrease in required dose, of provigil, NSAIDs or anything else by combining it with zolpidem and no one other than Applicant teaches the analgesic properties of zolpidem.

Claims 7 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Meisler (2000) in view of Holman (2002) in view of Malin, (US 5,084,007), Kaplan (US 4,501,745) and Kaplan (US 4,382,938).

In response, Applicants note that Meisler in no way teaches zolpidem to treat pain and that the additional references are not relevant to claims 4 and 5, reciting oral and topical administration, which limitations have been inserted into amended claim 1. Thus, this ground of rejection as to claims 7 and 8 is believed to have been overcome.

No fees are believed due in filing these papers. If any fees are due, the Commissioner is authorized to charge payment of any additional fees or credit any overpayment to Deposit Account No. 03-0678.

Serial No. 10/764,857
Docket No. 763510-3

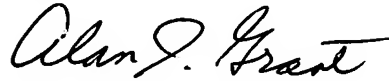
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 11/19/07
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Respectfully submitted,



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